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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER	
ENEWOLD,J	
ART UNIT	**PAPER NUMBER**
1655	17

DATE MAILED: 03/21/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	08/981,998	PULST, STEFAN M.	
	Examiner	Art Unit	
	Jeanine A Enewold	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☐ Responsive to communication(s) filed on *3/7/00* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *37, 44-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *37, 44-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

14) ☐ Notice of References Cited (PTO-892)
15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
16) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
17) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
18) ☐ Notice of Informal Patent Application (PTO-152)
19) ☐ Other: .

DETAILED ACTION

1. Currently Claims 37, 44-58 are pending.

2. This action is a substitute action because a first office action on the merits was sent, February 2, 2000, prior to the preliminary amendment entry which cancelled Claims 1-36, 38-43 and added Claims 44-58.

Election/Restrictions

3. Applicant's election of Group I, Claims 1-15, 27-29, 37, 40, 43 in Paper No. 14 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Priority

4. Claims 48-58, are given priority of 5/8/96. Claims 37, 44-47 are given priority to the instant application, filing date of 5/11/98, because all of the claims contain SEQ ID NO: 4 and 5 which were first disclosed in the instant application. SEQ ID NO:s 1-3 were first disclosed in the parent application 08/727,084, files 10/8/96. The priority to the 371 application also does not disclose the instant SEQ ID NO:s 4 and 5.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 37 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for identifying nucleic acids encoding a human SCA2 protein by contacting a sample containing nucleic acids with a labeled probe which is specific for SCA2 wherein the probe specifically hybridizes to SEQ ID NO: 2 , does not reasonably provide enablement for a method for identifying nucleic acids encoding a human SCA2 protein by contacting a sample containing nucleic acids with a labeled probe comprising at least 15 nucleotides capable of specifically hybridizing with a sequence of nucleic acids of the nucleotide sequence set forth in SEQ ID NO: 2 or SEQ ID NO: 4 under high stringency conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims.

The claims are broadly drawn to a method for identifying nucleic acids encoding a human SCA2 protein by contacting a sample containing nucleic acids with a labeled probe comprising at least 15 nucleotides capable of specifically hybridizing with a sequence of nucleic acids of the nucleotide sequence set forth in SEQ ID NO: 2 or SEQ ID NO: 4 under high stringency conditions.

The specification teaches an isolated nucleic acid encoding the human SCA2 protein (pg. 6) and an isolated nucleic acid encoding the mouse SCA2 protein. The specification teaches SEQ ID NO: 1 and 2 which are the human nucleic acid and the

corresponding polypeptide for SCA2, respectively. SEQ ID NO: 3 and 4 are the mouse nucleic acid and the corresponding polypeptide for SCA2, respectively. The specification teaches that the ataxin-2 related protein, A2RP, has a 42 amino acid domain which is 86% identical between the two proteins (pg. 11, 32, 47).

A comparison of the human SCA2 gene to the mouse SCA2 gene indicates that the two sequences are only 88% identical. Further, the human SCA2 protein is 91% identical to the mouse SCA2 protein (see attachment). A method for identifying nucleic acids encoding a human SCA2 protein would be unpredictable by detecting SEQ ID NO: 4 since the murine gene is 88% identical to the human SCA2 gene.

The art teaches there are numerous spinocerebellar ataxia genes which contain trinucleotide repeats. Orr et al. (US Pat. 5,741,645) teaches that SCA1 gene contains CAG trinucleotide repeats (abstract). A method for identifying nucleic acids encoding a human SCA2 protein with a probe comprising at least 15 nucleotide capable of specifically hybridize with SEQ ID NO: 2 would be unpredictable since the SCA1 gene identified by Orr contains more than 19 CAG repeat units (over 57 nucleotides) which would specifically hybridize to a probe comprising at least 15 nucleotides between 657 and 723 of SEQ ID NO: 2.

The claims as written do not require that the "at least 15 nucleotides capable of specifically hybridizing with a nucleic acids sequence" are contiguous. Therefore, the claims encompass many sequences which would bear little resemblance to the SCA2 nucleic acid of the invention. Neither the specification nor the claims set forth any

particular structural or functional characteristics that a skilled artisan could use to identify polynucleotides that constitute a probe comprising at least 15 nucleotides capable of specifically hybridizing with a sequence of nucleotides of SEQ ID NO: 2 or SEQ ID NO: 4.

Since it is known in the art that human and mouse genes are only 88% identical, the human and mouse SCA2 protein, SEQ ID NO: 3 and SEQ ID NO; 5 are only 91% identical and an ataxin-2 related protein has 86% identity to the SCA2 protein there is unpredictability of the ability to detect a nucleic acids encoding a human SCA2 protein without detecting nucleic acids which encode for either ataxin-2 related protein or murine SCA2 protein by detecting SEQ ID NO: 4. In light of the 86% similarity of SCA2 protein to the ataxin-2 related protein, it is also unpredictable as to whether the human SCA2 would specifically hybridize to only SCA2 genes. Since the specification and the prior art do not provide any specific guidance to how to identify human SCA2 proteins without identifying A2RP or murine SCA2 proteins, the specification does not enable one skilled in the art to practice the invention without undue experimentation. Additionally, the identification of human SCA2 nucleic acids with a probe at least 15 nucleotides which specifically hybridize with SEQ ID NO: 2 or SEQ ID NO: 4 would be unpredictable because SCA1 contains CAG repeats which would specifically hybridize under stringent conditions to SEQ ID NO: 2 or SEQ ID NO:4. Therefore, neither the specification nor the art provides sufficient guidance for identifying all nucleic acids encoding a human SCA2 because only one gene was disclosed.

6. Claims 44-47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for identifying nucleic acids encoding a human SCA2 protein by contacting a sample with a probe to identify compounds which hybridize thereto, wherein the nucleic acids encoding a human SCA2 protein comprises at least 36 CAG repeats at 12q24.1, does not reasonably provide enablement for a method for identifying nucleic acids encoding a human SCA2 protein by contacting a sample with a probe to identify compounds which hybridize thereto, wherein the nucleic acids encoding a human SCA2 protein comprises a mutation at 12q24.1 and a method wherein the mutation is an expanded CAG repeat. Further, while being enabling for a method for identifying nucleic acids encoding a human SCA2 protein by contacting a sample containing nucleic acids with a labeled probe which is specific for SCA2 wherein the probe specifically hybridizes to SEQ ID NO: 2 , does not reasonably provide enablement for a method for identifying nucleic acids encoding a human SCA2 protein by contacting a sample containing nucleic acids with a labeled probe comprising at least 15 nucleotides capable of specifically hybridizing with a sequence of nucleic acids of the nucleotide sequence set forth in SEQ ID NO: 2 or SEQ ID NO: 4 under high stringency conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims.

The claims are broadly drawn to a method for identifying nucleic acids encoding a human SCA2 protein by contacting a sample containing nucleic acids with a labeled probe comprising at least 15 nucleotides capable of specifically hybridizing with a sequence of nucleic acids of the nucleotide sequence set forth in SEQ ID NO: 2 or SEQ ID NO: 4 under high stringency conditions to identify compounds which hybridize thereto, wherein the nucleic acids encoding a human SCA2 protein comprises a mutation at 12q24.1 and a method wherein the mutation is an expanded CAG repeat.

The specification teaches the number of CAG repeats required to indicate SCA2 is substantially above normal, preferably at least about 10-15 CAG repeats above normal (pg. 31, lines 3-5). The specification teaches that a normal individual has been found to have 22 or 23 CAG repeats. Further, the detection of at least 35 CAG repeats, or more preferably 37 CAG repeats indicates a patient afflicted with SCA2. Moreover, the study performed with SCA2 patients and 50 normal individuals revealed that the number of repeats in SCA2 patients ranged from 36-52 CAG repeats.

The specification teaches an isolated nucleic acid encoding the human SCA2 protein (pg. 6) and an isolated nucleic acid encoding the mouse SCA2 protein. The specification teaches SEQ ID NO: 1 and 2 which are the human nucleic acid and the corresponding polypeptide for SCA2, respectively. SEQ ID NO: 3 and 4 are the mouse nucleic acid and the corresponding polypeptide for SCA2, respectively. The specification teaches that the ataxin-2 related protein, A2RP, has a 42 amino acid domain which is 86% identical between the two proteins (pg. 11, 32, 47).

A comparison of the human SCA2 gene to the mouse SCA2 gene indicates that the two sequences are only 88% identical. Further, the human SCA2 protein is 91% identical to the mouse SCA2 protein (see attachment). A method for identifying nucleic acids encoding a human SCA2 protein would be unpredictable by detecting SEQ ID NO: 4 since the murine gene is 88% identical to the human SCA2 gene.

The art teaches there are numerous spinocerebellar ataxia genes which contain trinucleotide repeats. Orr et al. (US Pat. 5,741,645) teaches that SCA1 gene contains CAG trinucleotide repeats (abstract). A method for identifying nucleic acids encoding a human SCA2 protein with a probe comprising at least 15 nucleotide capable of specifically hybridize with SEQ ID NO: 2 would be unpredictable since the SCA1 gene identified by Orr contains more than 19 CAG repeat units (over 57 nucleotides) which would specifically hybridize to a probe comprising at least 15 nucleotides between 657 and 723 of SEQ ID NO: 2.

As written the claims broadly encompass all mutations which may include polymorphisms in the gene, frameshifts, deletions, substitutions and such which are not described in the specification or the art. The claims as written do not require that the "at least 15 nucleotides capable of specifically hybridizing with a nucleic acids sequence" are contiguous. Therefore, the claims encompass many sequences which would bear little resemblance to the SCA2 nucleic acid of the invention. Neither the specification nor the claims set forth any particular structural or functional characteristics that a skilled artisan could use to identify polynucleotides that constitute a probe comprising at least

15 nucleotides capable of specifically hybridizing with a sequence of nucleotides of SEQ ID NO: 2 or SEQ ID NO: 4.

The specification teaches that 92% of normal individuals have 22 CAG repeats in the SCA2 gene. A expansion of the CAG repeats may include the addition of one additional CAG repeat, 23 repeats in total. The specification, further teaches, that 8% of normal individuals have 23 repeats in the SCA2 gene. Since the specification does not provide a specific definition of "an expanded CAG repeat" and the claims are merely drawn to an expanded CAG repeat, identifying a nucleic acid encoding a human SCA2 protein based solely on the expansion of CAG is unpredictable. Further, the specification does not describe all mutations which may occur in the SCA2 locus. Therefore, undue experimentation would be required to practice the invention as claimed because the specification only provides guidance for identifying nucleic acids encoding mutant human SCA2 protein where the mutation is due to an expanded CAG repeat region wherein the expanded CAG repeat region is greater than 36 CAG repeats. The skilled artisan would be required to perform additional population studies and comparison studies to determine mutations in the SCA2 locus in 12q24.1. Further, since it is known in the art that human and mouse genes are only 88% identical, the human and mouse SCA2 protein, SEQ ID NO: 3 and SEQ ID NO; 5 are only 91% identical and an ataxin-2 related protein has 86% identity to the SCA2 protein there is

unpredictability of the ability to detect a nucleic acids encoding a human SCA2 protein without detecting nucleic acids which encode for either ataxin-2 related protein or murine SCA2 protein by detecting SEQ ID NO: 4. In light of the 86% similarity of SCA2 protein to the ataxin-2 related protein, it is also unpredictable as to whether the human SCA2 would specifically hybridize to only SCA2 genes. Since the specification and the prior art do not provide any specific guidance to how to identify human SCA2 proteins without identifying A2RP or murine SCA2 proteins, the specification does not enable one skilled in the art to practice the invention without undue experimentation. Additionally, the identification of human SCA2 nucleic acids with a probe at least 15 nucleotides which specifically hybridize with SEQ ID NO: 2 or SEQ ID NO: 4 would be unpredictable because SCA1 contains CAG repeats which would specifically hybridize under stringent conditions to SEQ ID NO: 2 or SEQ ID NO:4. Therefore, neither the specification nor the art provides sufficient guidance for identifying all nucleic acids encoding a human SCA2 because only one gene was disclosed.

7. Claims 52-53 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for identifying nucleic acids encoding a human SCA2 protein by contacting a sample with a probe to identify compounds which hybridize thereto, wherein the nucleic acids encoding a human SCA2 protein comprises

at least 36 CAG repeats at 12q24.1, does not reasonably provide enablement for a method for identifying nucleic acids encoding a human SCA2 protein by contacting a sample with a probe to identify compounds which hybridize thereto, wherein the nucleic acids encoding a human SCA2 protein comprises a mutation at 12q24.1 and a method wherein the mutation is an expanded CAG repeat. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims.

The claims are broadly drawn to a method for identifying nucleic acids encoding a human SCA2 protein by contacting a sample with a probe to identify compounds which hybridize thereto, wherein the nucleic acids encoding a human SCA2 protein comprises a mutation at 12q24.1 and a method wherein the mutation is an expanded CAG repeat.

The specification teaches the number of CAG repeats required to indicate SCA2 is substantially above normal, preferably at least about 10-15 CAG repeats above normal (pg. 31, lines 3-5). The specification teaches that a normal individual has been found to have 22 or 23 CAG repeats. Further, the detection of at least 35 CAG repeats, or more preferably 37 CAG repeats indicates a patient afflicted with SCA2. Moreover, the study performed with SCA2 patients and 50 normal individuals revealed that the number of repeats in SCA2 patients ranged from 36-52 CAG repeats.

As written the claims broadly encompass all mutations which may include polymorphisms in the gene, frameshifts, deletions, substitutions and such which are not described in the specification or the art.

The specification teaches that 92% of normal individuals have 22 CAG repeats in the SCA2 gene. A expansion of the CAG repeats may include the addition of one additional CAG repeat, 23 repeats in total. The specification, further teaches, that 8% of normal individuals have 23 repeats in the SCA2 gene. Since the specification does not provide a specific definition of "an expanded CAG repeat" and the claims are merely drawn to an expanded CAG repeat, identifying a nucleic acid encoding a human SCA2 protein based solely on the expansion of CAG is unpredictable. Further, the specification does not describe all mutations which may occur in the SCA2 locus. Therefore, undue experimentation would be required to practice the invention as claimed because the specification only provides guidance for identifying nucleic acids encoding mutant human SCA2 protein where the mutation is due to an expanded CAG repeat region wherein the expanded CAG repeat region is greater than 36 CAG repeats. The skilled artisan would be required to perform additional population studies and comparison studies to determine mutations in the SCA2 locus in 12q24.1.

8. Claims 48-51 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for identifying nucleic acids encoding a human SCA2 protein by contacting a sample from a human containing nucleic acids

with a labeled probe which is specific for SCA2 wherein the probe specifically hybridizes to SEQ ID NO: 2, does not reasonably provide enablement for a method for identifying nucleic acids encoding a human SCA2 protein by contacting a sample containing nucleic acids with a labeled probe comprising at least 15 nucleotides capable of specifically hybridizing with a sequence of nucleic acids of the nucleotide sequence set forth in SEQ ID NO: 2 nucleotides 163-657 or nucleotides 724-4098 under high stringency conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims.

The claims are broadly drawn to a method for identifying nucleic acids encoding a human SCA2 protein by contacting a sample containing nucleic acids with a labeled probe comprising at least 15 nucleotides capable of specifically hybridizing with a sequence of nucleic acids of the nucleotide sequence set forth in SEQ ID NO: 2 nucleotides 163-657 or nucleotides 724-4098 under high stringency conditions.

The specification teaches an isolated nucleic acid encoding the human SCA2 protein (pg. 6) and an isolated nucleic acid encoding the mouse SCA2 protein. The specification teaches SEQ ID NO: 1 and 2 which are the human nucleic acid and the corresponding polypeptide for SCA2, respectively. SEQ ID NO: 3 and 4 are the mouse nucleic acid and the corresponding polypeptide for SCA2, respectively. The specification teaches that the ataxin-2 related protein, A2RP, has a 42 amino acid domain which is 86% identical between the two proteins (pg. 11, 32, 47).

A comparison of the human SCA2 gene to the mouse SCA2 gene indicates that the two sequences are only 88% identical. Further, the human SCA2 protein is 91% identical to the mouse SCA2 protein (see attachment). A method for identifying nucleic acids encoding a human SCA2 protein would be unpredictable since the murine gene is 88% identical to the human SCA2 gene.

The claims as written do not require that the "at least 15 nucleotides capable of specifically hybridizing with a nucleic acids sequence" are contiguous. Therefore, the claims encompass many sequences which would bear little resemblance to the claimed invention. Neither the specification nor the claims set forth any particular structural or functional characteristics that a skilled artisan could use to identify polynucleotides that constitute a probe comprising at least 15 nucleotides capable of specifically hybridizing with a sequence of nucleotides of SEQ ID NO: 2 nucleotides 163-657 or nucleotides 724-4098 under . Since it is known in the art that human and mouse genes are 88% identical, the human and mouse SCA2 protein, SEQ ID NO: 3 and SEQ ID NO; 5 are 91% identical and an ataxin-2 related protein has 86% identity to the SCA2 protein there is unpredictability of the ability to detect a nucleic acids encoding a human SCA2 protein without detecting nucleic acids which encode for either ataxin-2 related protein or murine SCA2 protein. In light of the 86% similarity of SCA2 protein to the ataxin-2 related protein, it is also unpredictable as to whether the human SCA2 would specifically hybridize to only SCA2 genes. Since the specification and the prior art do

not provide any specific guidance to how to identify human SCA2 proteins without identifying A2RP or murine SCA2 proteins, the specification does not enable one skilled in the art to practice the invention without undue experimentation. Additionally, the identification of human SCA2 nucleic acids with a probe at least 15 nucleotides which specifically hybridize with SEQ ID NO: 2 nucleotides 163-657 or nucleotides 724-4098 under would be unpredictable because SCA1 contains CAG repeats which would specifically hybridize under stringent conditions to SEQ ID NO: 2 or SEQ ID NO:4. Therefore, neither the specification nor the art provides sufficient guidance for identifying all nucleic acids encoding a human SCA2 because only one gene was disclosed.

9. Claim 58 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for identifying nucleic acids encoding a human SCA2 protein by contacting a sample containing nucleic acids with a labeled probe which is specific for SCA2 wherein the probe specifically hybridizes to SEQ ID NO: 2, does not reasonably provide enablement for a method for identifying nucleic acids encoding a human SCA2 protein by contacting a nucleic acids with primers which amplify at least a nucleic acid fragment of SEQ ID NO: 2 containing nucleotides 658-723 and detecting the amplification product. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims.

The claims are broadly drawn to a method for identifying nucleic acids encoding a human SCA2 protein by contacting a nucleic acids with primers which amplify at least a nucleic acid fragment of SEQ ID NO: 2 containing nucleotides 658-723 and detecting the amplification product.

The specification teaches that nucleotides 658-723 of SEQ ID NO: 2 are the CAG repeat region.

The art teaches there are numerous spinocerebellar ataxia genes which contain trinucleotide repeats. Orr et al. (US Pat. 5,741,645) teaches that SCA1 gene contains CAG trinucleotide repeats (abstract). A method for identifying nucleic acids encoding a human SCA2 protein with a probe comprising at least 15 nucleotide capable of specifically hybridize with SEQ ID NO: 2 would be unpredictable since the SCA1 gene identified by Orr contains more than 19 CAG repeat units (over 57 nucleotides) which would specifically hybridize to a probe comprising at least 15 nucleotides between 657 and 723 of SEQ ID NO: 2.

Since it is known in the art that the SCA1 gene contains CAG repeats greater than 19 repeats. The identification of human SCA2 nucleic acids with a probe at least 15 nucleotides which specifically hybridize with SEQ ID NO: 2 or SEQ ID NO: 4 would be unpredictable because SCA1 contains CAG repeats which would specifically hybridize under stringent conditions to SEQ ID NO: 2 or SEQ ID NO:4. Therefore, neither the specification nor the art provides sufficient guidance for identifying all nucleic acids encoding a human SCA2 because only one gene was disclosed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 45, 49, 53 are indefinite over the recitation "an expanded CAG repeat" because expanded is a relative term which may mean different things to those skilled in the art. Therefore, the metes and bounds of the claimed invention are unclear.

B) Claims 37, 44-53 are indefinite because it is unclear whether the claim is directed to a method of identifying any nucleic acid encoding a human SCA2 protein or whether the claim is directed to identifying mutant SCA2 proteins. The preamble states that the method is for identifying nucleic acids encoding a human SCA2 protein however, the final process step is identifying compounds which contain a mutation at the SCA2 locus in 12q24.1.

C) Claims 56-57 are indefinite over the recitation "nucleotides 163-657" and "nucleotides 724-4098" because the nucleotides have not been identified to a certain SEQ ID NO:. It is presumed that these nucleotides are relating to SEQ ID NO: 2.

D) Claim 58 is indefinite over the recitation "subject primers" because it is unclear what "subject primers" are. Further, "subject primers have not been defined in

the specification previously. Claim 58 is further indefinite over the recitation "contacting nucleic acid obtained from subject primers" because the claim never describes to what the "nucleic acid obtained from subject primers" is contacted with. Further, Claim 58 is indefinite over the recitation "at least a nucleic acid fragment of SEQ ID NO: 2 containing nucleotides 658-723 of SEQ ID NO: 2" because it is unclear whether the nucleic acid fragment must contain all nucleotides 658-723 and may also contain other fragments of SEQ ID NO: 2 or alternatively, a nucleic acid fragment of nucleotides 658-723 are encompassed by the instant claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 37, 44-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Pulst et al. (Nature Genetics, 1996).

Pulst et al. (herein referred to as Pulst) teaches a mouse sequence which is 100% identical to the nucleic acid sequence of SEQ ID NO: 4 nucleotides 50-3454 and thus would hybridize under high stringency conditions. Pulst also teaches a nucleic acid sequence which is 100% identical to the nucleic acid sequence of SEQ ID NO: 2 (limitations of Claim 6 and 10). Oligonucleotides were end-labeled, FISH was

performed and cDNA clones were isolated with P-labeled probes (pg. 275, col. 1). Pulst teaches several different methods for identifying nucleic acids encoding SCA2 protein including FISH, and hybridization of (CAG)10 oligonucleotides followed by cloning and sequencing (pg. 275)(limitations of Claim 37). Pulst teaches that the number of repeats was between 36-52 repeats (limitations of Claims 45-47). Pulst also teaches primers which were derived from SEQ ID NO: 2 and SEQ ID NO: 4 (pg. 275, para. 6).

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

12. Claim 37 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 37 of copending Application No. 09/083,268. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Conclusion

13. **No claims allowable.**

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

A) Trottier et al. "Polyglutamine expansion as a pathological epitope in Huntington's disease and four dominant cerebellar ataxias", Nature, vol 378, November 1995, p 403-406.

Trottier teaches that SCA2 is probably associated with CAG repeats, but the genes has not yet been identified.

B) Filla et al. "Has spinocerebellar ataxia type 2 a distinct phenotype?" Neurology, Vol 45, April 1995, pg. 793-796.

Filla teaches clinical features of patients diagnosed with SCA2. Filla teaches only molecular genetic analysis may distinguish the different forms of SCA (pg. 796).

C) Sanpei et al. "Identification of the spinocerebellar ataxia type 2 gene using DIRECT" Nature Genetics, Nov 1996, pg. 277-284.

Sanpei teaches a method for detecting expansion of SCA2 CAG repeats using DIRECT. Probes and primers were disclosed to detect the SCA2 gene.

D) Lee, US Patent 5,853,995, December 29, 1998.

Lee teaches large scale genotyping of diseases and a diagnostic test for spinocerebellar ataxia type 6. Lee teaches a method for screening individuals at risk for developing diseases caused by trinucleotide repeat

sequence instability by amplifying genomic DNA trinucleotide repeats sequences in a sample from an individual to be tested by PCR using primers, labeling a probe capable of detecting the amplified DNA trinucleotide repeat sequences, comparing to a control, to determine whether the individual tested may be at risk for developing diseases caused by trinucleotide repeat sequences, if the DNA trinucleotide repeat sequence is larger than the control trinucleotide repeat sequence.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Enewold whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Thursday from 7:00AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jeanine Enewold
March 20, 2000

LISA B. ARTHUR
PRIMARY EXAMINER
GROUP ~~1800~~ 1600